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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------|
| 10/087,112 | 03/01/2002 | Fuqiang Jin | PHA 2001US 08841.105031 | 6704 |
| 20786 | 7590 | 05/05/2004 | EXAMINER | |
| KING & SPALDING LLP 191 PEACHTREE STREET, N.E. ATLANTA, GA 30303-1763 | | | MCKENZIE, THOMAS C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,112

Applicant(s)

JIN ET AL.

Examiner

Thomas McKenzie Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 and 60-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-24, 26-46, 60, 61 and 63-65 is/are allowed.
- 6) ☒ Claim(s) 25 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/27/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to amendments filed on 2/27/04. Applicant has amended claims 1-46. Applicant has canceled claims 47-59. Claims 60-65 are new. There are fifty-two claims pending and fifty-two under consideration. Claims 25-28 and 62-65 are compound claims. Claims 1-24, 29-46, 60, and 61 are synthesis claims. This is the second action on the merits. The application concerns some syntheses of the anti-viral drug D4FC.

Response to Amendment

2. Applicants amended abstract overcomes the objection made in point #4 of the previous office action. Applicants' correction of an obvious typo overcomes the indefiniteness rejection made in point #6. Applicants' proviso, limiting Q to be other than acetate, overcomes the art rejection over Watanabe (J. Med. Chem.) made in point #7. However, that proviso raises issues of new matter, which are discussed below. Applicants are still claiming the propionate homologue of the compound taught in the reference, Watanabe (J. Med. Chem.). Normally, an intermediate taught by Watanabe (J. Med. Chem.) cannot be the basis of an obviousness rejection, but both the presently claimed compounds and the compound taught by the reference are intermediates used to prepare 5-fluorocytidine anti-viral compounds. That is both the claimed compounds and the prior art are in a highly analogous art. However, Applicants' presently claimed

propionate ester would not be suitable for the purpose intended by Watanabe (J. Med. Chem.). The reference was concerned with the synthesis of an antiviral compound with an acetate group at C-5 and Applicants' propionate intermediate would not be suitable for that purpose.

Applicants requirement that the Q group in formulas II* and III is limited to acyloxy-isoalkyl groups overcomes the art rejections over by Lopez ('339, Ref AA) and Shi (Journal of Medicinal Chemistry, Ref CA) in points #8 and #9. The rejection over Lopez ('339, Ref AA) should have been directed to formula (II*) not formula (II). The Examiner regrets the error.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to Inventor Jin's address. See 37 CFR 1.52(c).

Applicants' comment about obtaining a new oath is noted.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as reasonably to convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The proviso in the fifth line of claim 25 lacks description. Nowhere in the specification is such a relationship linking the description among radicals Q, R¹, and R⁴ described. Radical R⁴ also contains radical R¹. There is no suggestion that the choices for R¹ in radical Q and R⁴ are independent. Thus, Applicants proviso also affects R⁴. Such a negative limitation requires description. In *Ex parte Grasselli, et al.* 231 USPQ 393, decided June 30, 1983, the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences said: "we agree with the examiner's position of record that the negative limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112." "It might be added that the express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts."

Allowable Subject Matter

5. Claims 1-24, 26-46, 60, 61, and 63-65 are allowed. The following is a statement of reasons for the indication of allowable subject matter: Applicants comments about Chu ('514) are noted. Chu ('514) teaches a process of converting a thymidine compound into a 2',3'-dehydro nucleoside via an intermediate that has *cis* arrangement of the 2' and 3' substituents. Applicants claim a process of converting a cytidine compound into a 2',3'-dehydro nucleoside via an intermediate that has *trans* arrangement of the 2' and 3' substituents. While one cannot rule out the presence of small amounts of the *trans* intermediate in the process of Chu ('514), their postulate of carbonyl participation in the acylation reaction makes such *trans* material unlikely.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire

on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

8. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (703) 872-9306. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts

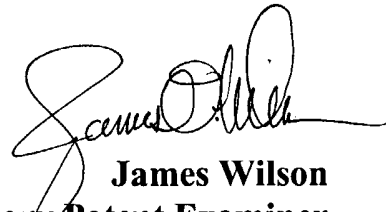
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to reach the Examiner by telephone are unsuccessful, please contact James O.

Wilson, acting SPE of Art Unit 1624, at (571)-272- 0661.

A handwritten signature in black ink, appearing to read "James Wilson", written in a cursive style.

James Wilson
Acting Supervisory Patent Examiner
Art Unit 1624

TCMcK/me 